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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/580,856	11/21/2006	Jacques Defaye	0508-1163	5988
465 7590 03/03/2009 YOUNG & THOMPSON 209 Madison Street Suite 500 ALEXANDRIA, VA 22314			EXAMINER LAU, JONATHAN S	
			ART UNIT 1623	PAPER NUMBER
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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary

Application No.

10/580,856

Applicant(s)

DEFAYE ET AL.

Examiner

Jonathan S. Lau

Art Unit

1623

Period for Reply -- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 24 November 2008.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 21-43 is/are pending in the application.
- 4a) Of the above claim(s) 21-34, 38, 40 and 42 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 35-37, 39, 41 and 43 is/are rejected.
- 7) ☒ Claim(s) 35-37, 39, 41 and 43 is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date _____
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date _____
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: _____

DETAILED ACTION

This Office Action is responsive to Applicant's Amendment and Remarks, filed 24 Nov 2008, in which claims 36 and 37 are amended to change the scope and breadth of the claim; claim 41 is amended to correct minor informalities; and withdrawn claims 21, 27, 29 and 34 are amended to change the scope and breadth of the claim.

This application is the national stage entry of PCT/FR04/02998, filed 24 Nov 2004; and claims benefit of foreign priority document FRANCE 0323873, filed 26 Nov 2003. An English language translation of this foreign priority document is of record.

Claims 21-43 are pending in the current application. Claims 21-34, 38, 40 and 42, drawn to non-elected inventions, are withdrawn.

Election/Restrictions

Applicant's traverse of the new grounds for finding of Lack of Unity detailed in the Office Action mailed 24 Jul 2008 in the Applicant's Amendment and Remarks filed on 24 Nov 2008 is acknowledged. The traversal is on the ground(s) that amended withdrawn claims do not encompass the specific compound disclosed by the prior art. This is not found persuasive because the finding of Lack of Unity is based special technical feature of a single general inventive concept, and the expression special technical features is defined as meaning those technical features that define the contribution which each claimed invention, considered as a whole, makes over the prior art with regard to both

novelty and inventive step. The invention as claimed does not recite a special technical feature of a single general inventive concept that define the contribution which each claimed invention, considered as a whole, makes over the prior art Charbonnier et al. with regard to both novelty and inventive step.

The requirement is still deemed proper and is therefore made FINAL.

Objections Withdrawn

Applicant's Amendment, filed 24 Nov 2008, with respect to objection to claim 41 has been fully considered and is persuasive, as amended claim 41 ends in a period.

This rejection has been **withdrawn**.

Rejections Withdrawn

Applicant's Amendment, filed 24 Nov 2008, with respect to Claims 35-37, 39, 41 and 43 rejected under 35 U.S.C. § 112, first paragraph, as failing to comply with the written description requirement has been fully considered and is persuasive, as amended claim 21 does not recite **derivatives** of an aromatic group or an amino acid **derivative**.

This rejection has been **withdrawn**.

Applicant's Amendment, filed 24 Nov 2008, with respect to 35-37, 39, 41 and 43 rejected under 35 U.S.C. 112, second paragraph, as being indefinite has been fully

considered and is persuasive, as amended claim 21 does not recite the exemplary language of "such as" and "for example".

This rejection has been **withdrawn**.

Claim Objections

Claims 35-37, 39, 41 and 43 are objected to because of the following informalities: Claims 35-37, 39, 41 and 43 recite within each claim multiple distinct inventions as detailed in the Requirement for Restriction mailed 13 Feb 2008. Claim 21, from which claims 35-37, 39, 41 and 43 depend, recites the invention of both Group I and Group II. Claims 35-37, 39, 41 and 43, because they depend from claim 21 and incorporate all limitations therein, recite the invention of both Group III and Group IV.

Response to Applicant's Remarks:

Applicant's Remarks, filed 24 Nov 2008, have been fully considered and found not to be persuasive.

It is noted that MPEP 800 is drawn to restriction in Applications filed under 35 USC 111. The instant application is a national stage entry of PCT/FR04/02998 under 35 USC 371. It is noted that, with regard to unity of Invention during the national stage, MPEP 1893.03(d) provides "Note: the determination regarding unity of invention is made without regard to whether a group of inventions is claimed in separate claims or as alternatives within a single claim. The basic criteria for unity of invention are the same, regardless of the manner in which applicant chooses to draft a claim or claims."

37 CFR 1.75(a) provides "The specification must conclude with a claim particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention or discovery." Claims 35-37, 39, 41 and 43 are objected to for not particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention or discovery because a group of inventions that are found to lack unity of invention are recited as alternatives within a single claim as detailed above.

The following are modified grounds of rejection necessitated by Applicant's Amendment, filed 24 Nov 2008, in which claims 36 and 37 are amended to change the scope and breadth of the claim; claim 41 is amended to correct minor informalities; and withdrawn claims 21, 27, 29 and 34 are amended to change the scope and breadth of the claim. Claims 35-37, 39, 41 and 43 depend from claim 21 and incorporate all limitations therein, including changes to the scope and breadth of the claim.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Amended Claims 35-37, 39, 41 and 43 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the

application was filed, had possession of the claimed invention. Claim 21 recites "R³ representing a substituent allowing hydrolysis of the carbamate group in order to release the amine function" at page 4, lines 11-12; "aromatic groups carrying substituents on the aromatic ring" at page 4, line 18; and "a biological recognition element" at page 4, line 21.

The specification discloses chemicals, such as R³ being tert-butyl or benzyl in claim 21 as originally filed, substituents such as methyl or hydroxyl in claim 21 as originally filed, and biological recognition elements such as a peptide or monosaccharide in claim 21 as originally filed which meet the written description and enablement provisions of 35 USC 112, first paragraph. However, claims 35-37, 39, 41 and 43 are directed to encompass substituent allowing hydrolysis of the carbamate group, substituents and biological recognition elements, which only correspond in some undefined way to specifically instantly disclosed chemicals. None of these substituent allowing hydrolysis of the carbamate group, substituents and biological recognition elements meet the written description provision of 35 USC § 112, first paragraph, due to lacking chemical structural information for what they are and because chemical substituent allowing hydrolysis of the carbamate group, substituents and biological recognition elements are highly variant and encompass a myriad of possibilities. The specification provides insufficient written description to support the genus encompassed by the claim. No limiting definition of substituent is provided, and the example provided does not limit a substituent of an aromatic group to substituents such as methyl, ethyl, chlorine, bromine, iodine, nitro, hydroxyl, methoxyl or acetamido.

The recitations, "substituent allowing hydrolysis of the carbamate group" and "biological recognition elements", are seen to be merely functional language.

Functional language at the point of novelty, as herein employed by Applicants, is admonished in *University of California v. Eli Lilly and Co.* 43 USPQ2d 1398 (CAFC, 1997) at 1406: stating this usage does "little more than outline goal appellants hope the recited invention achieves and the problems the invention will hopefully ameliorate". The CAFC further clearly states that "[A] written description of an invention involving a chemical genus, like a description of a chemical species, requires a precise definition, such as by structure, formula, [or] chemical name, of the claimed subject matter sufficient to distinguish it from other materials" at 1405(emphasis added), and that "It does not define any structural features commonly possessed by members of the genus that distinguish from others. One skilled in the art therefore cannot, as one can do with a fully described genus, visualize or recognize the identity of the members of the genus. A definition by function, as we have previously indicated, does not suffice to define the genus.." at 1406 (emphases added).

Thus, Applicants functional language at the points of novelty fails to meet the requirements set forth under 35 U.S.C. 112, first paragraph. Claims employing functional language at the exact point of novelty, such as Applicants', neither provide those elements required to practice the inventions, nor "inform the public during the life of the patent of the limited of monopoly asserted" (*General Electric Company v. Wabash Appliance Corporation et al.* 37 USPQ at 468 (US Supreme Court 1938)).

It is noted that the pharmaceutical art is unpredictable, requiring each embodiment to be individually assessed for physiological activity. *In re Fisher*, 427 F.2d 833, 166 USPQ 18 (CCPA 1970) indicates that the more unpredictable an area is, the more specific enablement is necessary in order to satisfy the statute. In the instant case, the instant claimed invention is highly unpredictable since one skilled in the art cannot fully described genus, visualize or recognize the identity of the members of the genus, by structure, formula, or chemical name, of the claimed subject matter, as discussed above in *University of California v. Eli Lilly and Co.* Hence, in the absence of fully recognizing the identity of the members genus herein, one of skill in the art would be unable to fully predict possible physiological activities of any compounds having claimed functional properties in the pharmaceutical compositions herein.

Vas-Cath Inc. v. Mahurkar, 19 USPQ2d 1111, makes clear that "applicant must convey with reasonable clarity to those skilled in the art that, as of the filing date sought, he or she was in possession of *the invention*. The invention is, for purposes of the 'written description' inquiry, *whatever is now claimed*." (See page 1117.) The specification does not "clearly allow persons of ordinary skill in the art to recognize that [he or she] invented what is claimed." (See Vas-Cath at page 1116.)

With the exception of the above specifically disclosed chemical structures, the skilled artisan cannot envision the detailed chemical structure of the encompassed substituent allowing hydrolysis of the carbamate group, substituents and biological recognition elements, regardless of the complexity or simplicity of the method of isolation. Adequate written description requires more than a mere statement that it is

part of the invention and reference to a potential method for isolating it. The chemical structure itself is required. See Fiers v. Revel, 25 USPQ2d 1601, 1606 (CAFC 1993) and Amgen Inc. V. Chugai Pharmaceutical Co. Ltd., 18 USPQ2d 1016. In Fiddes v. Baird, 30 USPQ2d 1481, 1483, claims directed to mammalian FGF's were found unpatentable due to lack of written description for the broad class. The specification provided only the bovine sequence. Finally, University of California v. Eli Lilly and Co., 43 USPQ2d 1398, 1404, 1405 held that:

...To fulfill the written description requirement, a patent specification must describe an invention and do so in sufficient detail that one skilled in the art can clearly conclude that "the inventor invented the claimed invention." *Lockwood v. American Airlines, Inc.*, 107 F.3d 1565, 1572, 41 USPQ2d 1961, 1966 (1997); *In re Gosteli*, 872 F.2d 1008, 1012, 10 USPQ2d 1614, 1618 (Fed. Cir. 1989) ("[T]he description must clearly allow persons of ordinary skill in the art to recognize that [the inventor] invented what is claimed."). Thus, an applicant complies with the written description requirement "by describing the invention, with all its claimed limitations, not that which makes it obvious," and by using "such descriptive means as words, structures, figures, diagrams, formulas, etc., that set forth the claimed invention." *Lockwood*, 107 F.3d at 1572, 41 USPQ2d at 1966.

Therefore, only the structurally defined chemical compounds, but not the full breadth of the claims, meet the written description provision of 35 USC § 112, first paragraph. The species specifically disclosed are not representative of the genus because the genus is highly variant. Applicant is reminded that Vas-Cath makes clear that the written description provision of 35 USC § 112 is severable from its enablement provision. (See Vas-Cath at page 1115.)

The court of *In re Curtis* held that "a patentee will not be deemed to have invented species sufficient to constitute the genus by virtue of having disclosed a single species when... the evidence indicates ordinary artisans could not predict the operability ... of any other species." (see *In re Curtis* 354 F.3d 1347, 69 USPQ2d 1274, Fed. Cir. 2004). The court of *Noelle v. Lederman* also pointed out that generic claim to

anti-CD40CR Mabs lacked written description support because there was no description of anti-human or other species Mabs, and no description of human CD40CR antigen. The court further pointed out that attempt to "define an unknown by its binding affinity to another unknown" failed. See 355 F.3d 1343, 69 USPQ2d 1508, Fed. Cir. 2004.

Claim Rejections - 35 USC § 103

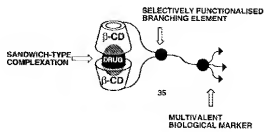
The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

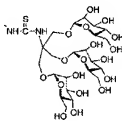
Amended Claims 35-37 are rejected under 35 U.S.C. 103(a) as being unpatentable over Ortiz-Mellet et al. (Chem. Eur. J. 2002, 8(9), p1982-1990, of record) in view of Kotter et al. (J. Chem. Soc., Perkin Trans. 1, 1998, p2193-2200, of record).

Ortiz-Mellet et al. discloses conjugates of a cyclodextrin dimer linked by a



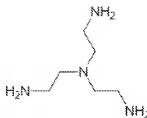
branching element to a biological marker,

1989, left column, structure 35 in Figure 4). Ortiz-Mellet et al. discloses the structure as a drug delivery system forming a 2:1 host-guest complex (page 1989, left column, paragraph 2). Ortiz-Mellet et al. discloses using the anticancer drug taxotere, a drug of the taxol family, as the guest compound (page 1989, left column, paragraph 1). Ortiz-



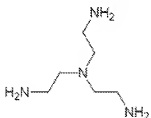
Mellet et al. discloses the biological marker moiety (page 1988, right column, scheme 7). Ortiz-Mellet et al. discloses it is advantageous that long enough spacer arms are used to warrant the accessibility of the glycocluster structure to carbohydrate-lectin recognition events and that substitution with numerous biological marker moieties may also impair inclusion and stabilization of potential guests (page 1988, right column, paragraph 1).

Ortiz-Mellet et al. does not specifically disclose the compound bis[2-[N'-(6¹-deoxycyclomaltoheptaos-6¹-yl)thiureido]ethyl] 2-[N'-[tris(2,3,4,6-tetra-O-acetyl-α-D-mannopyranosyloxy- methyl)methyl]thiureido]ethylamine (compound no. 6).



Kotter teaches the compound is a branching element known to be useful as a linker between saccharide moieties (column 2195, right column, scheme 5). Kotter teaches the compound is a linker useful in the field of carbohydrate protein interactions (page 2193, abstract and left column, paragraph 1).

It would have been obvious to one of ordinary skill in the art at the time of the invention to combine Ortiz-Mellet et al. in view of Kotter et al. Both Ortiz-Mellet et al. and Kotter et al. are drawn to the field of branching agents to link saccharide moieties for carbohydrate protein interactions. It is *prima facie* obvious to substitute the equivalent known for the same purpose of the branching element compound



taught by Kotter et al. for the branching element disclosed by Ortiz-Mellet et al. One of ordinary skill in the art would be motivated to combine Ortiz-Mellet et al. in view of Kotter et al. because Ortiz-Mellet et al. discloses it is advantageous that long enough spacer arms are used to warrant the accessibility of the glycluster structure to carbohydrate - lectin recognition events.

Response to Applicant's Remarks:

Applicant's Remarks, filed 24 Nov 2008, have been fully considered and found not to be persuasive.

Applicant notes that the branching element 20 taught by Kotter is shorter than the two other branching elements of compounds 13 and 17. However, "[t]he prior art's mere disclosure of more than one alternative does not constitute a teaching away from any of these alternatives because such disclosure does not criticize, discredit, or otherwise discourage the solution claimed.." *In re Fulton*, 391 F.3d 1195, 1201, 73 USPQ2d 1141, 1146 (Fed. Cir. 2004).', see MPEP 2123 II. The disclosure of branching elements of compounds 13 and 17 does not constitute a teaching away from the branching element 20 taught by Kotter.

Applicant notes that the synthesis of the instant invention is applicable to industrial synthesis as it does not require purifications. However, it is noted that the instant claims are drawn to the composition, and not the method of synthesis. MPEP 2144.04 VII provides guidance regarding the obviousness of products with respect to purity. Purer forms of known products may be patentable, but the mere purity of a product, by itself, does not render the product unobvious. *Ex parte Gray*, 10 USPQ2d 1922 (Bd. Pat. App. & Inter. 1989). Factors to be considered in determining whether a purified form of an old product is obvious over the prior art include whether the claimed chemical compound or composition has the same utility as closely related materials in the prior art, and whether the prior art suggests the particular form or structure of the claimed material or suitable methods of obtaining that form or structure. *In re Cofer*, 354 F.2d 664, 148 USPQ 268 (CCPA 1966). As the prior art teaches the same utility,

suggests the particular form or structure of the claimed material and suitable methods of obtaining that form or structure, the purity of the product, by itself, does not render the product unobvious.

Applicant notes Ortiz-Mellet teaches the cited linkers are not the best linkers for binding efficiency and Kotter teaches other linked cluster are more efficient. However, MPEP 2123 II also provides, "'A known or obvious composition does not become patentable simply because it has been described as somewhat inferior to some other product for the same use.'" *In re Gurley*, 27 F.3d 551, 554, 31 USPQ2d 1130, 1132 (Fed. Cir. 1994)". That Ortiz-Mellet and Kotter teach preferred embodiments that are somewhat superior to some other product for the same use does not necessarily constitute teaching away from the somewhat inferior obvious composition for the same use.

Amended Claims 39, 41 and 43 are rejected under 35 U.S.C. 103(a) as being unpatentable over Ortiz-Mellet et al. (Chem. Eur. J. 2002, 8(9), p1982-1990, of record) in view of Kotter et al. (J. Chem. Soc., Perkin Trans. 1, 1998, p2193-2200, of record) as applied to claims 35-37 above, and further in view of Hamada et al. (US Patent 5,684,169, issued 04 Nov 1997, of record).

Ortiz-Mellet et al. in view of Kotter et al. teaches as above.

Ortiz-Mellet et al. in view of Kotter et al. does not specifically teach a pharmaceutical composition comprising said compound no 6, or said composition in the form of an aqueous solution.

Hamada et al. teaches a pharmaceutical composition comprising a cyclodextrin inclusion complex of taxol (abstract). Hamada et al. teaches said complex prepared and used as an aqueous solution (column 3, lines 20-30 and column 4, lines 54-56). Hamada et al. teaches optimization of the dosage is within the level of one of the ordinary skill in the art (column 4, lines 44-47).

It would have been obvious to one of ordinary skill in the art to combine Ortiz-Mellet et al. in view of Kotter et al. and Hamada et al. Both Ortiz-Mellet et al. and Hamada et al. are in the field of the use of cyclodextrin inclusion complex of a taxol as a drug delivery system. Both Ortiz-Mellet et al. and Hamada et al. teach the improved solubility of a cyclodextrin inclusion complex of a taxol. (Ortiz-Mellet, page 1989, left column, paragraph 1; and Hamada, abstract). It would have been routine to one of ordinary skill in the art to formula a drug delivery system into a pharmaceutical composition. The limitation of instant claim 43, "characterized in that it contains per unit dose approximately 100 mg to approximately 750 mg of one of said complex." (emphasis added) is interpreted as an intended use of the instantly claimed pharmaceutical composition used to formulate a unit dose, not a structural limitation of said pharmaceutical composition. It is apparent from what is disclosed that the pharmaceutical composition taught by Ortiz-Mellet et al. in view of Kotter et al. and further in view of Hamada et al. is inherently capable of being formulated into a unit dose containing 100 mg to approximately 750 mg of one of said complex, meeting the functional limitation of instant claim 43. Further, Hamada et al. teaches that routine optimization of the dosage is within the level of one of the ordinary skill in the art.

Response to Applicant's Remarks:

Applicant's Remarks, filed 24 Nov 2008, have been fully considered and found not to be persuasive.

Response to Applicant's remarks regarding Ortiz-Mellet et al. in view of Kotter et al. are as above.

The following are new grounds of rejection necessitated by Applicant's Amendment, filed 24 Nov 2008, in which claims 36 and 37 are amended to change the scope and breadth of the claim; claim 41 is amended to correct minor informalities; and withdrawn claims 21, 27, 29 and 34 are amended to change the scope and breadth of the claim. Claims 35-37, 39, 41 and 43 depend from claim 21 and incorporate all limitations therein, including changes to the scope and breadth of the claim.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Amended Claim 36 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 36 recites ", or a sufficiently large size." at lines 7-10. Claim 36 as amended does not clearly relate the "sufficiently large size" to the clause "capable of interacting simultaneously with two cyclodextrin sub-units" because the comma may be

interpreted to indicate these clauses are unrelated. According to this interpretation, the term "sufficiently large size" renders the claim indefinite because the specification does not provide a standard for ascertaining what size is "sufficiently large" and one of ordinary skill in the art would not be reasonably apprised of the scope of the invention.

Conclusion

No claim is found to be allowable.

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Jonathan S. Lau whose telephone number is 571-270-

3531. The examiner can normally be reached on Monday - Thursday, 9 am - 4 pm EST.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Shaojia Anna Jiang can be reached on 571-272-0627. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

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Patent Examiner
Art Unit 1623

/Shaojia Anna Jiang/
Supervisory Patent Examiner
Art Unit 1623